

REMARKS

I. Introduction

Applicant respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 8-10, 17-19, 24, 26, 27, 30, 34 and 37 are requested to be cancelled. The cancellation of claims does not constitute acquiescence in the propriety of any rejection set forth by the Examiner. Applicant reserves the right to pursue the subject matter of the canceled claims in subsequent divisional applications.

Claims 1, 13-15, 21, 22, 25, 38, 40 and 41 are currently being amended. Exemplary support for the claim amendments is found throughout the specification. For example, support for a promoter sequence which is not coupled to its native enhancer sequence is found in the specification on page 10, line 11. Exemplary support for a promoter sequence which is capable of effecting the expression of the coding sequence is found in the specification on page 9, lines 3 and 4. Exemplary support for the nucleic acid not being in the form of a recombinant virus is found in the specification on page 5, line. Additionally, exemplary support for the antigen being of a viral, bacterial, parasite or fungal pathogen is found in originally filed claims 8 and 17.

A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Upon entry of this Amendment, claims 1-7, 11-16, 20-23, 25, 28, 29, 31-33, 35, 36, and 38-41 will remain pending in the application.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

II. Response to Issues Raised by Examiner in Outstanding Office Action

a. Claim Rejections - 35 U.S.C. § 112, First Paragraph

i. Rejection of Claims 1-8, 11-13, 15-17, 20-21, 23, 25, and 28-40

Claims 1-8, 11-13, 15-17, 20-21, 23, 25, and 28-40 are rejected by the Examiner under 35 U.S.C. § 112, first paragraph for lack of written description. Applicant respectfully requests reconsideration and withdrawal of the rejection.

The Examiner asserts that the specification fails to describe and to provide a representative number of species of a broad genus of minimal promoter. Applicant respectfully disagrees with the Examiner. However, to expedite prosecution, Applicant has deleted the term “minimal” from the claims. The claims, as amended, refer to promoter sequences and enhancer sequences. Since a person of ordinary skill in the art would know whether a given sequence was a promoter sequence or an enhancer sequence, the specification adequately describes the claimed invention and complies with the written description requirement of 35 U.S.C. § 112, first paragraph.

ii. Rejection of Claim 38

Claim 38 is rejected by the Examiner because this claim allegedly contains new matter. The Examiner asserts that the evidence provided in the specification is not reasonably extrapolated to a vaccine composition comprising a minimal promoter sequence operably linked to a coding sequence for an HIV antigen. Applicant respectfully disagrees. However, to expedite prosecution, Applicant has amended claim 38 by deleting reference to an HIV antigen. Therefore, claim 38, as amended, complies with the requirements of 35 U.S.C. § 112, first paragraph.

b. Claim Rejections - 35 U.S.C. § 102

i. Rejection of Claims 25 and 39-41 as Being Anticipated by Hofmann et al. (PNAS, 93:5185-5190, 1996)

Claims 25 and 39-41 are rejected by the Examiner under 35 U.S.C. § 102(b) as being anticipated by Hoffmann for the reasons of record. Applicant respectfully disagrees with the Examiner. However, to expedite prosecution, claim 25 has been amended to specify that the antigen is of a viral, bacterial, parasite or fungal pathogen. Support for the amendment is found in original claims 8 and 17. Such antigens are not disclosed or suggested in Hoffmann.

Therefore, the claimed invention is not anticipated by Hoffmann. Applicant respectfully requests reconsideration and withdrawal of the rejection.

ii. Rejection of Claims 25 and 39-41 as Being Anticipated by
Chao et al. (USP 6,368,825)

Claims 25 and 39-41 are rejected by the Examiner under 35 U.S.C. § 102(e) as being anticipated by Chao for the reasons of record. Applicant respectfully disagrees with the Examiner. However, to expedite prosecution, claim 25 has been amended to specify that the antigen is of a viral, bacterial, parasite or fungal pathogen. Support for the amendment is found in original claims 8 and 17. Such antigens are not disclosed or suggested in Chao. Therefore, the claimed invention is not anticipated by Chao. Applicant respectfully requests reconsideration and withdrawal of the rejection.

iii. Rejection of Claims 1-3, 5-8, 12-14, 25 and 37-41 as Being
Anticipated by Bujard et al. (USP 5,888,981)

Claims 1-3, 5-8, 12-14, 25 and 37-41 are rejected by the Examiner under 35 U.S.C. § 102(e) as being anticipated by Bujard. Applicant respectfully requests reconsideration and withdrawal of the rejection.

Bujard discloses constructs from which expression can be switched on and off under various conditions. The Examiner states that the promoters disclosed in Bujard would be encompassed by the present claims because he believes that the promoters disclosed in Bujard would express at low efficiency. However, column 39, lines 42 and 43 of Bujard state that the exemplified promoters are “virtually silent” when integrated in the proper genomic environment. In contrast, the present claims, as amended, require that the promoter sequence is capable of effecting the expression of the coding sequence and that the coding sequences are expressed in an amount sufficient to elicit an immune response. Exemplary support is found in the specification on page 9, lines 3-4. The “virtually silent” expression from the constructs of Bujard cannot be said to be expression which is sufficient to elicit an immune response to an antigen.

Furthermore, the present claims, as amended, specify that the antigen is of a viral, bacterial, parasite or fungal pathogen. Exemplary support is found in original claims 8 and 17. In contrast, Bujard does not disclose or suggest eliciting an immune response against the specified antigens.

For the reasons discussed above, the claimed invention is not anticipated by Bujard.

iv. Rejection of Claims 1-8, 11-12, 15-17, 20, 23, 25, 28, and 33-39 as Being Anticipated by Johnston et al. (USP 6,194,389)

Claims 1-8, 11-12, 15-17, 20, 23, 25, 28, and 33-39 are rejected by the Examiner under 35 U.S.C. § 102(e) as being anticipated by Johnston. Applicant respectfully disagrees with the Examiner. However, to expedite prosecution, Applicant has amended the claims to recite that the promoter sequence is not coupled to its native enhancer sequence. Exemplary support for the amendment is found in the specification on page 10, line 11. Johnston does not teach or suggest such a construct. Therefore, the claimed invention is not anticipated by Johnston. Applicant respectfully requests reconsideration and withdrawal of the rejection.

v. Rejection of Claims 1-4, 7-8, 11-17, 20-23, 25, 29-30, 32-34, 36-37, and 39-41 as Being Anticipated by Lai et al. (DNA Cell Biol., 14:643-651, 1995)

Claims 1-4, 7-8, 11-17, 20-23, 25, 29-30, 32-34, 36-37, and 39-41 are rejected by the Examiner under 35 U.S.C. § 102(b) as being anticipated by Lai. Applicant respectfully disagrees with the Examiner. However, to expedite prosecution, Applicant has amended the claims to recite that the promoter sequence is not coupled to its native enhancer sequence. Exemplary support for the amendment is found in the specification on page 10, line 11. Lai does not teach or suggest such a construct. Therefore, the claimed invention is not anticipated by Lai. Applicant respectfully requests reconsideration and withdrawal of the rejection.

vi. Rejection of Claims 25 and 39-41 as Being Anticipated by Haynes et al. (AIDS Res. Hum. Ret. 10, Supplement 2, pages S43-S45, 1994)

Claims 25 and 39-41 are rejected by the Examiner under 35 U.S.C. § 102 as being anticipated by Haynes. Applicant respectfully disagrees with the Examiner. However, to

expedite prosecution, Applicant has amended the claims to recite that the promoter sequence is not coupled to its native enhancer sequence. Exemplary support for the amendment is found in the specification on page 10, line 11. Haynes does not teach or suggest such a construct. Therefore, the claimed invention is not anticipated by Haynes. Applicant respectfully requests reconsideration and withdrawal of the rejection.

vii. Rejection of Claims 1-3, 7-8, 12-13, 25, 37, and 39-40 as Being Anticipated by Cochran (USP 5,047,237)

Claims 1-3, 7-8, 12-13, 25, 37, and 39-40 are rejected by the Examiner under 35 U.S.C. § 102 as being anticipated by Cochran. Applicant respectfully disagrees with the Examiner. However, to expedite prosecution, Applicant has amended the claims to recite that the promoter sequence is not coupled to its native enhancer sequence. Exemplary support for the amendment is found in the specification on page 10, line 11. Cochran does not teach or suggest such a construct. Therefore, the claimed invention is not anticipated by Cochran. Applicant respectfully requests reconsideration and withdrawal of the rejection.

viii. Rejection of Claims 1-3, 7-8, 12-14, 25, 28, and 37-41 as Being Anticipated by Fischer (USP 6,156,567)

Claims 1-3, 7-8, 12-14, 25, 28, and 37-41 are rejected by the Examiner under 35 U.S.C. § 102 as being anticipated by Fischer. Applicant respectfully disagrees. However, to expedite prosecution, Applicant has amended the claims to recite that the construct is not in the form of a recombinant virus. Exemplary support is found in the specification on page 5, line 2. In contrast, Fischer discloses a construct within a CAV viral vector. Therefore, the claimed invention is not anticipated by Fischer. Applicant respectfully requests reconsideration and withdrawal of the rejection.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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